





Patent Docket P0998D1

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Jeffrey L. Cleland et al.

Serial No.: 09/273,230

Filed: March 18, 1999

For: PROTEIN FORMULATION

Group Art Unit: 1643

Examiner: Christopher Yaen

Confirmation No: 6833

CUSTOMER NO: 09157

#### CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria. VA 22313-1450 on

August <u>3</u>, 2006

Anna Kan

## **INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

### 37 CFR §1.97(b)

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR § 1.53(d); or
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR§1.491, or
- before the mailing of the first Office action on the merits; or
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

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### [X] 37 CFR §1.97(c)

• by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below.

# [] 37 CFR §1.97(d)

• after the period specified in CFR § 1.97(c), and is accompanied by the fee set forth in 37 CFR § 1.17(p) and a statement as specified in 37 CFR § 1.97(e), as checked below.

[If either of boxes 37 CFR § 1.97(c) or 37 CFR § 1.97(d) is checked above, the following statement under 37 CFR § 1.97(e) may need to be completed.]

- [] 37 CFR §1.97(e) Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- [X] 37 CFR §1.704(d) Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filling of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filling of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- [X] The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) and/or publication(s) is set forth on the attached revised Form PTO-1449. Copies of the items listed on the PTO-1449 form are supplied herewith, except for United States patent(s) and United States patent application publication(s) and other documents that are marked with an asterisk (\*) in the attached PTO-1449 form. Copies of United States patents and United States patent application publications will not be supplied unless requested by the Office [37 CFR §1.98(a)(2)(ii)]. See Final Rule 1287 OG (October 12, 2004). Other documents cited with an asterisk have not been supplied because they were previously cited by or submitted to the Office

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in prior application Serial No. 08/615,369, filed March 14, 1996 and benefit from the prior application is claimed in this application under 35 U.S.C § 120. However, copies of any cited document will be provided in its entirety at the request of the Office.

#### [] BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-()" (nucleotide) and "BLAST Results B-1 - B-()" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

[X] not given

- [] given for each listed item
- [] given for only non-English language listed item(s) [Required]
- in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTEÇH, INC.

Date: August 3, 2006

Wendy M. Lee- Reg. No. 40,378 Telephone No. (650) 225-1994

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LIST OF DISCLOSURES CITED APPLICANT  Cleland et al.									
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	*316	4,597,966	01.07.86	Zolton et al.					
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)  [Hora et al., "Lyophilized formulations of recombinant tumor necrosis factor" Pharmaceutical Research									
	317	9(1):33-36 (Jan 1	1992)						
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